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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/644,027

08/19/2003

George N. Pavlakis

015280-257300US

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08/21/2008

TOWNSEND AND TOWNSEND AND CREW, LLP

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EXAMINER

PARKIN, JEFFREY S

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

08/21/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/644,027

Applicant(s)

PAVLAKIS, GEORGE N.

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3 and 5-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3 and 5-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date: _____

Detailed Office Action

Status of the Claims

Acknowledgment is hereby made of receipt and entry of the communication filed 09 May, 2008. Claims 3 and 5-11 are pending in the instant application.

Claim Objections

The previous objection to claims 3 and 5-11 is hereby withdrawn in response to applicant's amendment.

35 U.S.C. § 103(a)

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3 and 5-11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Pavlakis et al. (1999)¹ in view of Myers et al. (1995) and Benson et al. (1998). The amended claims are directed toward a nucleic acid construct comprising a modified simian immunodeficiency virus (SIV) gag gene. The gene has been

¹ Applicants are advised that this application claims priority to U.S. Application No. 07/858,747, filed 37 March, 1992. This application is not

modified in such a manner that inhibitory sequences (INS) that inhibit expression have been modified thereby presumably leading to increased gene expression. The modified sequence was prepared from the prototypical SIV isolate MAC239.

Pavlakis et al. (1999) disclose a detailed method for the elimination of inhibitory/instability regions in the human immunodeficiency type 1 (HIV-1) *gag* gene. Specifically, Pavlakis and colleagues disclose the following: 1) the identification of mRNAs containing INS; 2) localization/characterization of instability determinants; 3) mutation of the inhibitory/instability regions to generate stable mRNAs; and, 4) determination of the stability of the mutated RNA (see cols. 12-24). The authors noted that INS regions frequently contain high AU content and that mutating these regions without changing the coding capacity leads to a more stable mRNA that is translated more efficiently. This teaching does not disclose INS regions in SIV_{MAC239} or nucleic acid constructs/vectors comprising the modified SIV *gag* gene set forth in SEQ ID NO.: 4.

Myers et al. (1995) provide the complete nucleotide sequence of the *gag* gene from various prototypical HIV-2/SIV isolates including SIV_{MAC239}. This teaching does not identify INS regions within the gene of interest.

Benson et al. (1998) provide pharmaceutical compositions comprising recombinant constructs encoding SIV Gag and demonstrate that said compositions were useful at inhibiting viral replication in macaques (see Abstract, p. 4170). This

teaching also does not identify INS regions within the gene of interest.

However, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to extend the teachings of Pavlakis *et al.* (1999) to prototypical SIV isolates, as provided by Myers *et al.* (1995), since this would enable one of ordinary skill in the art to identify similar INS regions in prototypical SIV *gag* genes. One of ordinary skill in the art would have been motivated to modify these regions using the disclosed methodology since this would result in SIV *gag* mRNAs that can be expressed more efficiently. One of ordinary skill in the art would have been further motivated to include this modified coding regions in art-recognized vaccine vectors, such as those provided by Benson *et al.* (1998). The inclusion of these modified genes would reasonably be expected to result in increased translational efficiency and stronger immune responses.

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce R. Campell, Ph.D., can be reached at (571) 272-0974. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the

Application Number: 10/644,027

Docket No.: 015280-257300US

Applicant: Pavlakis, G. N.

Filing Date: 08/19/2003

Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

/Jeffrey S. Parkin, Ph.D./
Primary Examiner, Art Unit 1648

18 August, 2008